JAN 2 0 2011

510(k) Summary
for the Sorin Group Deutschland GmbH
Stöckert Centrifugal Pump (SCP) Plus System

(21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SPONSOR/APPLICANT

Sorin Group Deutschland GmbH
Lindberghstrasse 25
D-80939 Munich
Germany
Contact Person: Renate Goebert
Telephone: 011 +49 (0)89 323 01 153

Date Prepared: January 17, 2011

2. DEVICE NAME

Proprietary Name:	Stöckert Centrifugal Pump (SCP) Plus System
Common/Usual Name:	Cardiopulmonary bypass centrifugal pump
Classification Name:	Cardiopulmonary bypass speed control device (*21 CFR 870.4380; Product Code: DWA*)

3. PREDICATE DEVICE/S

- Stöckert Centrifugal Pump (SCP) Plus System - K091008

4. DEVICE DESCRIPTION

- **Physical description**
  The SCP Plus System is intended for use as a component part of or optional accessory to the S3 and S5 System (or any compatible system using the S5 firmware versions of 3.0. or greater) and with the Stöckert Air Purge (APC) System. The System consists of the drive unit, a mounting receptacle for the pump head, a retaining key, splash protection, and a 3-joint mast holder with fast clamp connector.

- **How the device functions**
  The Stöckert Centrifugal Pump (SCP) Plus System consists of hardware, firmware, and electronics that are used to drive the centrifugal pump for surgical procedures requiring cardiopulmonary bypass for typical durations of six (6) hours or less. The SCP drive unit uses magnetic coupling with the centrifugal pump.

- **Scientific concepts that form the basis for the device**
  The SCP Plus System with the loaded single use and disposable centrifugal pump recirculates the contents of the extracorporeal circuit during cardiopulmonary bypass.

- **Significant physical and performance characteristics of the device, such as device design, material used, and physical properties**
  The design, materials, and physical properties of the SCP Plus are unchanged from that already cleared by the FDA.

5. INTENDED USE/INDICATION FOR USE

The Stöckert Centrifugal Pump System is a cardiopulmonary bypass speed control device (21CFR 870.4380) that is indicated for use with the Cobe Revolution® Pump Head/Dideco Synergy™/ECC.O™ for speed controlled pumping through a cardiopulmonary bypass circuit for typical durations of six hours or less. The SCP Plus is intended for use as a component part of or optional accessory to the S3 and S5 System (or any compatible system using the S5 firmware versions of 3.0. or greater) and the Stöckert Air Purge Control (APC) System.

The SCP Plus has been qualified only for typical durations of six hours or less, appropriate to cardiopulmonary bypass procedures and has not been qualified through in vitro, in vivo, or clinical studies for long-term use as a bridge to transplant, pending recovery of the natural heart, or extracorporeal membrane oxygenation (ECMO) procedures.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE/S

The technological characteristics of the Stöckert Centrifugal Pump (SCP) Plus System described in this Traditional 510(k) Premarket Notification are identical to that reviewed by the FDA in K091008. They use the same hardware, firmware, and electronics as well as the same components including the drive unit, control panel, flow probe, emergency drive unit, flexible drive shaft, and connection cables.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No comparative non-clinical testing served as the basis for substantial equivalence.

The Stöckert Centrifugal Pump (SCP) Plus System was tested in conjunction with the heart lung machine for safety in accordance with IEC60601-1 (with National

Deviations), for electromagnetic compatibility in accordance with IEC60601-1-2, and performance according to a formal prospectively defined functional acceptance test. Testing of the Stöckert Centrifugal Pump (SCP) Plus System (hardware, firmware, and performance) has demonstrated that the Stöckert Centrifugal Pump (SCP) Plus System fulfills prospectively defined performance criteria and that the System meets user needs.

8. Summary of Clinical Testing as Basis for Substantial Equivalence

Formal clinical testing of the Stöckert Centrifugal Pump (SCP) Plus System has not been performed. Therefore, this section does not apply.

9. Summary of other Information

No information other than that described was included in this 510(k).

10. Conclusions Drawn From Non-clinical and Clinical Tests

Based on the non-clinical testing provided in this premarket notification, the Stöckert Centrifugal Pump (SCP) Plus System integrated with the Stöckert S5 performs in an identical manner as the System integrated with the Sorin C5 System, thus demonstrating that there are no differences and that the devices are substantially equivalent and perform in accordance with specifications and meets user needs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Sorin Group Deutschland GmbH
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

JAN 20 2011

Re: K103468
Trade/Device Name: Stöckert Centrifugal Pump (SCP) Plus System (SCP Plus)
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: II
Product Code: DWA
Dated: November 24, 2010
Received: November 24, 2010

Dear Ms. Robinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K103468

Device Name: Stöckert Centrifugal Pump (SCP) Plus System

Indications for Use:

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103468